# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

**CIVIL ACTION** 

AMERICAN SALES COMPANY, INC.,

MEIJER, INC., MEIJER DISTRIBUTION,

INC., on behalf of themselves and all others

v.

similarly situated,

Plaintiffs, : NO. 08-CV-03149

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SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE PLC, GSK,

Defendant.

November 10, 2010 Anita B. Brody, J.

## **MEMORANDUM**

Flonase is the brand-name version of fluticasone propionate ("FP")—a nasal corticosteroid produced by Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline PLC ("GSK"). The Food and Drug Administration ("FDA") approved Flonase to treat nasal inflammation caused by seasonal and non-seasonal allergies. Until recently, Flonase was one of the nation's top-selling drugs, generating sales well over \$1 billion in its peak years. This case concerns allegations that GSK restrained competition in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, by delaying the entry of generic FP into the market. Plaintiffs, American Sales Company, Inc., Meijer, Inc., and Meijer Distribution, Inc. (collectively, the "Direct Purchasers"), bring suit as direct purchasers of Flonase who were allegedly overcharged for

Flonase as a result of GSK's actions.<sup>1</sup> Direct Purchasers now move for class certification under Fed. R. Civ. P. 23(b)(3), proposing a class of: "all persons or entities in the United States and its territories who purchased and/or paid for Flonase nasal spray directly from Defendant (or any of its predecessors or affiliates) at any time from May 19, 2004 until the anticompetitive effects of Defendant's conduct ceased" (the "Proposed Class").

Although Defendant does not contest the Direct Purchasers' Motion for Class

Certification, recent Third Circuit precedent makes clear that I must "consider carefully all relevant evidence and make a definitive determination that the requirements of Rule 23 have been met before certifying a class." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 320 (3d Cir. 2008). After considering all of the relevant evidence, I conclude that Direct Purchasers have met their burden under Rule 23. I will therefore grant Direct Purchasers' Motion for Class Certification.<sup>2</sup>

#### I. BACKGROUND<sup>3</sup>

## A. The Hatch-Waxman Act and the Generic Drug Approval Process

In order to market a drug in the United States, a company must file a "New Drug Application" ("NDA") with the FDA. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301,

<sup>&</sup>lt;sup>1</sup> Also pending before me are two related actions: <u>Roxane Labs., Inc. v. GSK</u>, No. 09-CV-1638 (E.D. Pa. filed Apr. 17, 2009), brought by a generic competitor of GSK, and <u>IBEW - NECA Local 505 Health & Welfare Plan v. GSK</u>, No. 08-CV-3301 (E.D. Pa. filed July 14, 2008), brought by indirect purchasers of Flonase. This Class Certification Motion concerns only the Direct Purchasers' suit.

<sup>&</sup>lt;sup>2</sup> Jurisdiction over this action is proper under 28 U.S.C. §§ 1331, and 1337(a), and Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2.

<sup>&</sup>lt;sup>3</sup> The facts are stated based on evidence offered to support Direct Purchasers' Complaint.

et seq. (1994). In 1984, Congress enacted the Hatch-Waxman Act ("Hatch-Waxman"), which amended the Federal Food, Drug, and Cosmetics Act, and created an expedited approval process for generic drugs. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in various sections of titles 15, 21, 35, and 42 of the U.S. Code), as amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtits. A-B, 117 Stat. 2066, 2448-64 (codified at 21 U.S.C. § 355 (Supp. III 2003)). Under Hatch-Waxman, a company applying to make a generic version of a compound listed in the Orange Book need only file an Abbreviated New Drug Application ("ANDA"), requiring a demonstration of a certain level of bioequivalence to a listed drug instead of clinical trials. 21 U.S.C. § 355(j). The FDA issues public bioequivalence guidance for various categories of generic drugs. This guidance informs the public of the bioequivalence standards that ANDAs must meet in order to be approved. The FDA regularly modifies their bioequivalence guidance for specific categories of drugs.

While an ANDA is pending before the FDA, any interested party can file a citizen petition (a "Petition") with the FDA to register a complaint about the pending application. 21 C.F.R. §§ 10.25(a), 10.30. Until 2007, the FDA was required to consider and respond to every Petition.<sup>4</sup> For this reason, filing a Petition necessarily delayed the approval of any pending ANDA—only after the FDA responded to all pending Petitions could an ANDA be approved.

<sup>&</sup>lt;sup>4</sup> In 2007, after the Petitions at issue in this case were filed, Congress passed a law allowing the FDA to summarily dismiss Petitions, in order to prevent pharmaceutical companies from using this process to delay generic entry into the market. See 21 U.S.C. § 355(q)(1)(A)(ii).

## **B.** Flonase

GSK developed Flonase in the early 1980s, filing a patent in the United Kingdom in 1980, and in the United States in 1981. See U.S. Patent No. 4,335,121 (filed Feb. 13, 1981). Flonase was first released in Europe in 1991 under the trade name Flixonase. GSK subsequently filed NDA #20-121, requesting approval to release the drug in the United States. In October 1994, the FDA approved GSK's NDA to treat nasal inflammation caused by seasonal and non-seasonal allergies. GSK released Flonase in the United States in 1995, and it quickly became the most prescribed nasal steroid inhalant in the United States. By 2000, Flonase commanded 38% of brand-name inhaled nasal steroid sales in the United States, resulting in over \$600 million in sales. By 2005, the peak year for Flonase sales and the last year of GSK's market exclusivity, Flonase sales exceeded \$1.3 billion.

By the time Flonase's market exclusivity was set to expire, GSK had identified a number of generic pharmaceutical manufacturers intent on filing ANDAs and bringing competitive generic FP nasal sprays to the market. This case concerns GSK's alleged "brand maturation strategy," crafted to maintain Flonase's market dominance in the face of inevitable generic competition.

## C. GSK's Allegedly Anti-Competitive Conduct<sup>5</sup>

Direct Purchasers offer evidence that GSK's alleged "brand maturation strategy" included four tactics to delay the entry of generic FP nasal sprays into the market. First, Direct Purchasers

<sup>&</sup>lt;sup>5</sup> This discussion will be limited to Direct Purchasers' claims as they relate to the issue of class certification. This Memorandum does not exhaustively explore the merits of Direct Purchasers' case.

allege that GSK improperly influenced the FDA's bioequivalence guidance process. GSK allegedly encouraged the FDA to refrain from approving any FP ANDAs before it issued final bioequivalence guidance governing FP ANDAs. GSK then sought to slow the issuance of final bioequivalence guidance. GSK also petitioned the FDA to set extremely rigorous bioequivalence requirements using strict new tests that generic manufacturers would struggle to satisfy.

Second, Direct Purchasers provide evidence that GSK filed several Petitions with the FDA regarding pending FP ANDAs in order to force the FDA to respond and delay approval. Direct Purchasers allege that these Petitions were frivolous and only served to delay ANDA approval, rather than to raise genuine concerns with the applications.

Third, Direct Purchasers allege that GSK drafted an FP monograph for submission to the United States Pharmacopeia ("USP"), an "independent compendium of drug standards whose authority is recognized by reference in federal law." Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 388 (5th Cir. 2008). USP monographs list tests, procedures, and acceptance criteria in order to set standards for the quality, purity, strength, and consistency of the pharmaceutical ingredients in an approved drug. USP monographs also set standards that imported drugs must meet, and generally inform the pharmaceutical community about the acceptable standards for any pharmaceutical product. By drafting a USP monograph with rigorous standards, Direct Purchasers claim that GSK attempted to raise the bar for generic competitors and make it more difficult and thereby more costly to enter the market.

Finally, Direct Purchasers provide evidence that GSK supplemented its original NDA in an attempt to delay the FDA from approving any ANDAs before approving GSK's supplements.

This action would necessarily delay ANDA approval, because the ANDAs could not be approved

while the FDA was considering modifying the underlying NDA. Additionally, GSK hoped that the supplements would make generic entry into the market even more difficult because GSK's NDA supplements contained additional requirements for FP nasal sprays. Direct Purchasers argue that GSK used each of these four tactics to illegally maintain monopoly power in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

# II. LEGAL STANDARD

Subsection (a) of Fed. R. Civ. P. 23 lists four prerequisites for any class action: numerosity, commonality, typicality, and adequacy. Fed. R. Civ. P. 23(a). Subsection (b) specifies additional requirements for each type of class action. For certification under subsection (b)(3), the movant must also show "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). These requirements are called predominance and superiority.

In In re Hydrogen Peroxide, the Third Circuit clarified the standard of review for Motions for Class Certification. The court held that "proper analysis under Rule 23 requires rigorous consideration of all the evidence and arguments offered by the parties." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 321 (3d Cir. 2008). A district court must "consider carefully all relevant evidence and make a definitive determination that the requirements of Rule 23 have been met before certifying a class." Id. at 320. Further, "the court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits . . . [and] [f]actual determinations necessary to make Rule 23 findings must be made by a preponderance of the evidence." Id. at 307, 320. Finally, "[w]eighing conflicting expert testimony at the

demands." <u>Id.</u> at 323. "[A] district court may find it unnecessary to consider certain expert opinion with respect to a certification requirement, but it may not decline to resolve a genuine legal or factual dispute" relevant to class certification. <u>Id.</u> at 324.

Here, GSK does not dispute assertions made by Direct Purchasers, or Direct Purchasers' class certification experts. Nonetheless, "[a] party's assurance to the court that it intends or plans to meet the requirements [of Rule 23] is insufficient." <u>Id.</u> at 318. As such, I must still carefully consider Direct Purchasers' evidence to ensure that the requirements of Rule 23 have been met.

#### III. Discussion

Direct Purchasers seek to certify a class of "all persons or entities in the United States and its territories who purchased and/or paid for Flonase nasal spray directly from Defendant (or any of its predecessors or affiliates) at any time from May 19, 2004 until the anticompetitive effects of Defendant's conduct ceased." Below I consider all of the evidence and arguments offered by the parties relevant to class certification. Cf. In re Hydrogen Peroxide, 552 F.3d at 321.

## A. Rule 23(a)

I first consider the numerosity, commonality, typicality, and adequacy requirements of Rule 23(a). These prerequisites must be satisfied in order to bring any class action. I consider each prerequisite in turn.

## 1. Numerosity

The first prerequisite in Rule 23(a) requires that the class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "No minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." Stewart v. Abraham, 275 F.3d 220, 226-27 (3d Cir. 2001). As Stewart noted, however, a class smaller than 40 can also satisfy the numerosity requirement. In fact, courts have regularly found the numerosity requirement satisfied with classes far smaller than 40 people. In re K-Dur Antitrust Litig., 2008 WL 2699390, at \*3 (D.N.J. Apr. 14, 2008) (discussing approved classes of as few as ten members); Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd., 246 F.R.D. 293, 206 (D.D.C. 2007) (29 members sufficient); Feret v. Corestates Fin. Corp., No. 97-CV-6759, 1998 WL 512933, at \*6 (E.D. Pa. Aug. 18, 1998) (25 members sufficient); Town of New Castle v. Yonkers Contracting Co., 131 F.R.D. 38, 40-41 (S.D.N.Y. 1990) (29 members sufficient); Manning v. Princeton Consumer Discount Co., Inc., 390 F. Supp. 320, 324 (E.D. Pa. 1975) (14 members sufficient); Phila. Elec. Co. v. Anaconda Am. Brass Co., 43 F.R.D. 452, 463 (E.D. Pa. 1968) (25 members sufficient).

The touchstone of the numerosity inquiry is not the number of plaintiffs, but the practicability of joining those plaintiffs. <u>Jackson v. Southeastern Penn. Transp. Auth.</u>, 260 F.R.D. 168, 186 (E.D. Pa. 2009). Practicability "is a subjective determination based on number, expediency, and inconvenience of trying individual suits." <u>Id.</u> Practicability also depends on the geographic dispersion of the proposed class. <u>See Vinson v. Seven Seventeen HB Phila. Corp.</u>, No. 00-CV-6334, 2001 WL 1774073, at \*17 (E.D. Pa. Oct. 31, 2001) ("Joinder of these [11]

individuals alone is severely impracticable, not because of their number, but because of their geographical dispersion.").

Here, the Proposed Class consists of 33 members dispersed across 14 different states. This Court and others have found numerosity established in cases with 30 or more plaintiffs. Moreover, as in <u>Vinson</u>, joinder of these 33 members separately would be impracticable considering their geographic dispersion across several different states. I therefore find that numerosity has been established.

## 2. Commonality

The second prerequisite in Rule 23(a) requires that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). "However, where an action is to proceed under Rule 23(b)(3), the commonality requirement is subsumed by the predominance requirement... [because] it is far more demanding than the Rule 23(a)(2) commonality requirement." <u>Danvers Motor Co., Inc. v. Ford Motor Co.,</u> 543 F.3d 141, 148 (3d Cir. 2008) (internal quotation marks omitted); <u>In re Ins. Brokerage Antitrust Litig.</u>, 579 F.3d 241, 266 (3d Cir. 2009). Therefore I discuss the commonality requirement along with my analysis of Rule 23(b)(3)'s predominance requirement. See infra Part IV. B.1.

## 3. Typicality

The third prerequisite in Rule 23(a) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). Typicality does not require that the claims be identical. <u>In re Wellbutrin SR Direct Purchaser Antitrust Litig.</u>, 2008 WL 1946848, at \*3 (E.D. Pa. May 2, 2008). Rather, the typicality inquiry asks "whether the named plaintiffs' claims are typical, in common-sense terms, of the class, thus

suggesting that the incentives of the plaintiffs are aligned with those of the class." <u>Beck v.</u> <u>Maximus, Inc.</u>, 457 F.3d 291, 295-96 (3d Cir. 2006) (internal quotation marks omitted).

"The typicality requirement is intended to preclude certification of those cases where the legal theories of the named plaintiffs potentially conflict with those of the absentees." Georgine v. Amchem Prods., Inc., 83 F.3d 610, 631 (3d Cir. 1996). "The inquiry assesses whether the named plaintiffs have incentives that align with those of absent class members so that the absentees' interests will be fairly represented." Id. Further, a "proposed class representative is neither typical nor adequate if the representative is subject to a unique defense that is likely to become a major focus of the litigation." Beck, 457 F.3d at 301; McDonough v. Toys "R" Us, Inc., 638 F. Supp. 2d 461, 476 (E.D. Pa. 2009) (considering whether plaintiffs were "subject to unique defenses that preclude typicality"). Nonetheless, "[f]actual differences will not defeat typicality if the named plaintiffs' claims arise from the same event or course of conduct that gives rise to the claims of the class members and are based on the same legal theory." Danvers Motor Co., Inc. v. Ford Motor Co., 543 F.3d 141, 150 (3d Cir. 2005) (emphasis omitted); In re K-Dur Antitrust Litig., 2008 WL 2699390, at \*6 (D.N.J. Apr. 14, 2008) ("Although individual damages may differ, [Direct Purchasers' antitrust] claims are based on the same legal theory as the class. . . . [Therefore,] Direct Purchasers have satisfied the typicality requirement of Rule 23(a)(3)").

Here, Direct Purchasers' claims and GSK's defenses revolve around an identical course of conduct—GSK's allegedly monopolistic "brand maturation strategy." This strategy was implemented by GSK without reference to individual purchasers, and resulted in overcharges to all members of the Proposed Class. Although the Direct Purchasers may have paid different

prices for the product, affecting the amount of damages, the conduct causing the alleged injury was identical for all members of the Proposed Class.

Similarly, GSK's defenses concern its own conduct and do not relate to the actions of the individuals in the Proposed Class. As such, GSK offers no "unique defenses" that would preclude a finding of typicality. Because I find that members of the Proposed Class would complain of identical misconduct based on the same legal theories, and that their claims are not subject to any unique defenses, I conclude that typicality has been satisfied.

## 4. Adequacy

The fourth prerequisite in Rule 23(a) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). Whether adequacy has been satisfied "depends on two factors: (a) the plaintiff's attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class." New Directions Treatment Servs. v. City of Reading, 490 F.3d 293, 313 (3d Cir. 2007). Direct Purchasers' lead counsel has presented evidence of its experience in complex antitrust class actions, including several cases concerning Hatch-Waxman and antitrust claims involving generic pharmaceuticals. After reviewing Direct Purchasers' evidence, I conclude that Direct Purchasers' counsel are "qualified, experienced, and generally able to conduct the proposed litigation." New Directions, 490 F.3d at 313.

Second, the absence-of-conflict requirement "seeks to uncover conflicts of interest between named parties and the class they seek to represent." <u>In re Warfarin Sodium Antitrust Litig.</u>, 391 F.3d 516, 532 (3d Cir. 2004) (internal quotation marks omitted). "A class representative must be part of the class and possess the same interest and suffer the same injury

as the class members." <u>Amchem Products, Inc. v. Windsor</u>, 521 U.S. 591, 625-26 (1997) (internal quotation marks omitted). Adequacy will not be denied simply "because of a potential conflict of interest that may not become actual." <u>Kohen v. Pac. Inv. Mgmt. Co. LLC</u>, 571 F.3d 672, 680 (7th Cir. 2009).

GSK has not raised any conflicts within the Proposed Class. Moreover, as with most delayed generic entry cases, "because all class members have the right to pursue overcharge damages, they have the same incentive to do so, and there is no conflict among class members allegedly harmed by the same antitrust violation." In re Wellbutrin SR Direct Purchaser

Antitrust Litig., 2008 WL 1946848, at \*6 (E.D. Pa. May 2, 2008). Finally, any member of the Proposed Class that wishes to opt out of the class will be given an opportunity to do so. Because I conclude that the Proposed Class suffers from no conflicts, and is represented by qualified counsel, I conclude that the Proposed Class satisfies both prongs of the adequacy requirement.

# **B.** Rule 23(b)(3)

Once the Rule 23(a) prerequisites are satisfied, I must consider whether the class action may be maintained under Rule 23(b). Here Direct Purchasers request certification under section (b)(3), requiring proof of predominance and superiority. Direct Purchasers must show "that the questions of law or fact common to class members predominate over any questions affecting only individual members," and "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Matters pertinent include: "the class members' interests in individually controlling the prosecution or defense of separate actions," "the extent and nature of any litigation concerning the controversy already begun by or against class members," "the desirability or undesirability of concentrating the litigation of the

claims in the particular forum," and "the likely difficulties in managing a class action." Fed. R. Civ. P. 23(b)(3)(A)-(D).

#### 1. Predominance

Rule 23(b)(3) requires that "[i]ssues common to the class must predominate over individual issues." Fed. R. Civ. P. 23(b)(3). Issues are common or individual based on the nature of evidence that will suffice to resolve the issue. In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008). Thus "a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." Id. (internal quotation marks omitted). "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 172 (3d Cir. 2001). Therefore, "the task for plaintiffs at class certification is to demonstrate that [each] element . . . is capable of proof at trial through evidence that is common to the class rather than individual to its members." In re Hydrogen Peroxide, 552 F.3d at 311-12.

Predominance requires some inquiry into the merits. See In re Hydrogen Peroxide, 552 F.3d at 311. Plaintiffs bring suit under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. To successfully make out a claim under Section 2, Direct Purchasers must prove at a class-wide level: (a) that GSK's actions violated Section 2; (b) that the Proposed Class suffered antitrust impact as a result; and (c) measurable Class damages. Id.

# (a) Violation of Section 2

Section 2 of the Sherman Act has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as

distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 75 (3d Cir. 2010) (quoting Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481 (1992)). The key question at this stage is whether both elements can be proved with class-wide evidence. In re Hydrogen Peroxide, 552 F.3d at 311.

Here, Direct Purchasers' Section 2 claim requires proof of GSK's actions and intent.

Such proof will necessarily be classwide—GSK's actions did not vary with respect to individual direct purchasers, aside from the price charged. Their alleged "brand maturation strategy" governed their responses to pending ANDAs, rather than their relationships with individual direct purchasers. The evidence thus should be identical for all 33 members of the Proposed Class. I find that Direct Purchasers satisfy this prong of the predominance inquiry.

## (b) Antitrust Impact

In order to recover for a Section 2 violation, a plaintiff must also show that it suffered a loss caused by a defendant's antitrust violation. Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100, 114 n.9 (1969). This requires a plaintiff to show "individual injury resulting from [a] violation" of antitrust law—"also known as antitrust impact." In re Hydrogen Peroxide, 552 F.3d at 311. "In antitrust cases, impact often is critically important for the purpose of evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof." Id.

Antitrust impact requires a showing of "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." 2660 Woodley Rd. Joint Venture v. ITT Sheraton Corp., 369 F.3d 732, 738 (3d

Cir. 2004) (internal quotation marks omitted). In <u>In re Hydrogen Peroxide</u>, the Third Circuit made clear that a court considering class certification cannot simply assume antitrust impact. <u>In re Hydrogen Peroxide</u>, 552 F.3d at 325. Rather, the court must carefully consider conflicting evidence and expert testimony, and make a full and reasoned decision as to whether plaintiffs can prove antitrust impact on a class-wide basis.

Direct Purchasers claim that they were injured through overcharges as a result of delayed generic entry into the market. They present evidence tending to show the impact resulting from generic entry—that is, Direct Purchasers offer evidence showing that immediately after an approved generic product hits the market, direct wholesale purchasers change their purchasing behavior and substitute away from the branded product and towards the cheaper generic product. Delayed genetic entry into the market necessarily injures those direct purchasers, because those purchasers are forced to pay for the more expensive branded drugs.

To support this argument, Direct Purchasers present expert declarations from Drs.

Meredith Rosenthal and Jeffrey Leitzinger. Both experts look to: (1) the economic literature concerning the market for generic pharmaceuticals; (2) GSK's own projections estimating the substitution of generic FP for Flonase; and (3) actual data describing the rate and magnitude of Direct Purchasers' generic substitution. Using these three sources, both experts conclude that generic entry results in immediate substitution away from the branded drug to the cheaper generic drug, and that such substitution actually occurred in the market for FP. Dr. Leitzinger further provides a statistical analysis showing that this substitution would have occurred if generic entry had occurred earlier. These uncontested expert reports, then, show that if generic FP had been available earlier, Direct Purchasers would have quickly switched to generic FP. As a result, they

were injured by GSK's allegedly anticompetitive conduct resulting in delayed entry. After considering Plaintiff's detailed expert declarations, I conclude that Direct Purchasers should be able to prove class-wide antitrust injury, and that this prong of the predominance inquiry is satisfied.

## (c) Measurable Damages

The final prong of the predominance inquiry requires that Direct Purchasers measure aggregate damages to the Class using class-wide evidence. For class certification purposes, "[i]t is not necessary to show with total certainty the amount of damages sustained . . . ." Rossi v. Standard Roofing, Inc., 156 F.3d 452, 483 (3d Cir. 1998). A court's inquiry is instead "limited to whether or not the proposed methods are so insubstantial as to amount to no method at all." In re Wellbutrin SR Direct Purchaser Antitrust Litig., 2008 WL 1946848, at \*9 (E.D. Pa. May 2, 2008) (quoting In re Potash Antitrust Litig., 159 F.R.D. 682, 697 (D. Minn. 1995)); In re Vitamins Antitrust Litig., 209 F.R.D. 251, 268 (D.D.C. 2002) ("At the certification stage, the preliminary inquiry in assessing the proposed methods of proving damages is limited: The inquiry is not whether the methods are valid, but is only to assess whether the methods are available to prove damages on a class-wide basis.").

Direct Purchasers have identified a "before-and-after method" of calculating aggregate damages using a benchmark to compare actual data with modeled data in a world absent Defendant's anticompetitive conduct. (Pls.' Mem. Supp. Mot. Summ. J. at 48; Joseph Meltzer Decl. Ex. 4, Rosenthal Decl. ¶ 23-30). This method has been recognized as a "judicially recognized and commonly accepted" method of modeling classwide antitrust damages, and has

previously served as the basis for a finding of predominance on the question of damages. <u>In re K-Dur Antitrust Litig.</u>, 2008 WL 2699390, at \*20 (D.N.J. Apr. 14, 2008).

Specifically, Dr. Rosenthal suggests using the prices and substitution rates that prevailed in 2006, after generic FP was actually introduced, and using those rates to estimate the effect of generic entry in 2004 and 2005, when Direct Purchasers contend that generic FP would have entered the market to drive down prices, but for GSK's conduct. (Joseph Meltzer Decl. Ex. 4, Rosenthal Decl. ¶ 31). Using this data, Dr. Rosenthal calculates the aggregate amount by which the Proposed Class was allegedly overcharged as a result of GSK's anticompetitive conduct. Id. ¶¶ 32-36. This analysis was performed on a class-wide basis, and did not require individualized data. I do not challenge that Dr. Rosenthal's proposed method of aggregating damages represents an appropriate, classwide measure of damages to the Direct Purchasers. I therefore find that Direct Purchasers have satisfied the predominance requirement of Rule 23(b)(3).

## 2. Superiority

Finally, Rule 23(b)(3) requires that a class action be "superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). Assessing superiority requires a court "to balance, in terms of fairness and efficiency, the merits of a class action against those of 'alternative available methods' of adjudication." Georgine v. Amchem Prods., Inc., 83 F.3d 610, 632 (3d Cir. 1996). Courts have readily found superiority established in other delayed generic entry antitrust cases. See In re Wellbutrin, 2008 WL 1946848, at \*10-\*11 ("In the instant case, denying certification would require each direct purchaser to file suit individually at the expense of judicial economy and litigation costs for each party."); In re K-Dur, 2008 WL 2699390, at \*20-\*21.

Both fairness and efficiency dictate that I certify the class in this case. If all 33 members of the Proposed Class were to file suit individually, all of the parties involved, and the courts required to hear each suit, would expend significant resources to resolve identical issues.

Additionally, because common questions predominate here, re-trying the case individually would leave all parties vulnerable to unfair inconsistencies. I agree with the vast majority of district courts that in a delayed generic entry antitrust case such as this, a class action is superior to other methods of adjudication. I therefore find that the requirements of Rule 23(b)(3) have been met.

## C. Notice

Finally, because this is an action under Rule 23(b)(3), I must "direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable efforts." Fed. R. Civ. P. 23(c)(2)(B). Generally speaking, where there is a relatively small number of parties in the class, delivering notice "via first class mail to the last known address in defendant's records . . . [is] the most efficient and effective means for reaching individual members of the class." Parks v. Portnoff Law Assocs., 243 F. Supp. 2d 244, 250 (E.D. Pa. 2003). I agree with Direct Purchasers that it will be relatively simple to ascertain the identity and mailing address of the 33 members of the Proposed Class here. At the class certification hearing, I directed Direct Purchasers to submit Proposed Notice for approval. After Proposed Notice has been submitted, I will confirm that the Proposed Notice comports with the requirements in Rule 23(c)(2)(B)(i)-(vii).

#### V. Conclusion

For the reasons explained above, I conclude that Direct Purchasers have carried their burden under Rules 23(a) and (b)(3). I will therefore grant Direct Purchasers' Motion for Class Certification. The Class to be certified shall consist of:

all persons or entities in the United States and its territories who purchased and/or paid for Flonase nasal spray directly from Defendant (or any of its predecessors or affiliates) at any time from May 19, 2004 until the anticompetitive effects of Defendant's conduct ceased.

I will also order that Direct Purchasers submit to this Court Proposed Notice comporting with the requirements in Rule 23(c)(2)(B) by November 24, 2010.

		s/Anita B. Brody	
		ANITA B. BRODY, J.	
Copies VIA ECF on	to:	Copies <b>MAILED</b> on	to: